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UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 5,015,758, was filed on July 26, 1996, under 35 U.S.C. § 156. U.S. Patent No. 5,015,758 issued on May 14, 1991 from an application that was filed on September 6, 1989.

The assistance of your Office is requested in confirming that the product identified in the application, DIFFERIN Topical Gel, 0.1%, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. However, it is noted that another application for patent term extension for the above-identified patent has been filed based upon the regulatory review period of the product DIFFERIN Solution, 0.1% and that the regulatory review periods of both DIFFERIN Solution, 0.1% and DIFFERIN Topical Gel, 0.1% have also been relied upon for applications for patent term extension for the patents Re. 34,440, 4,717,720 and 5,212,303.

Inquiries regarding this communication should be directed to Karin Tyson at (703) 306-3159.

Hiram A. Bernstein
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